R marks/Argum nts:

By this Amendment, applicants have requested that a typographical error in the spelling of the name of one inventor, namely Maria Janusz, be corrected. Also by this Amendment, applicants have amended claims 15, 24, 27 and 31 and have added new claims 58-68 to the application. Accordingly, claims 15, 16, 24, 26-32, 35, 40, 41, 54 and 58-68 are pending in the application.

Summary of Interview

No agreement regarding the allowability of any claims was reached during a July 29, 2003 telephonic interview between the counsel for applicants and Examiner Roy R. Teller and Supervisor Brenda G. Brumback. However, agreement was reached during the interview that claims 40, 41 and 54 are not presently the subject of any rejection. The allowability of such claims requires additional consideration.

As was discussed in the interview, in an effort to expedite consideration of the present application, by this Amendment applicants have deleted all references to the phrase "neurodegenerative diseases" from the claims. Moreover, new claims have been added to separately claim the treatment of dementia and Alzheimer's Disease via the administration of Colostrinin in isolated form to human pateints. Applicants reserve the right to pursue the canceled subject matter in one or more divisional applications.

Claim Rejections - 35 U.S.C. §112

In the Office action of February 7, 2003 (Paper No. 26), the Examiner rejected claims 15, 16, 24, 26-32 and 35 under 35 U.S.C. §112, first paragraph, on grounds that

the specification, while enabling for Colostrinin usage as a modest cytokine inducer in human leukocytes does not reasonably provide enablement for treatment of dementia, neurodegenerative diseases or Alzheimer's Disease. The Examiner contends that the specification does not enable any person skilled in the art to make and/or use the invention commensurate in scope with the claims. Applicants respectfully disagree.

The specification clearly identifies what the term "Colostrinin" refers to (e.g., page 4, line 13 to page 5, line 11) and from what sources Colostrinin may be derived (e.g., page 4, lines 8-12). Furthermore, the specification provides a stepwise explanation of how Colostrinin may be isolated from mammalian colostrum (e.g., page 5, line 12 to page 6, line 16). And, in what form it can be administered to human patients (e.g., page 6, line 30 to page 7, line 13).

The specification discloses that Colostrinin can be administered to human patients to treat dementia (e.g., page 2, line 15) and Alzheimer's Disease (e.g., page 2, line 20), and that it can be used as a dietary supplement (e.g., page 3, line 23 to page 4, line 4). In addition, the specification identifies the preferred and most preferred therapeutic unit or dosage to be administered to human patients (e.g., page 6, lines 27-29), as well as the preferred administration regimen or method of treating human patient's with Colostrinin (e.g., page 6, lines 18-26). In addition to disclosing the preferred treatment regimen and therapeutic unit or dosage, the specification discloses the various forms in which the Colostrinin can be administered to a human patient (e.g., page 6, line 30 to page 7, line 13).

Example I (page 10, line 20 to page 12, line 9) shows how to obtain Colostrinin from the colostrum of sheep taken after parturition up to 24 hours after commencement of lactation. Example III (page 12, line 23 to page 13, line 16) shows how to prepare a tablet for sucking comprising Colostrinin for use in treating human patients afflicted with the early and late stages of dementia and Alzheimer's Disease. Example VII (page 15, line 6 to page 18, line 3) shows that administration of Colostrinin in tablet form as taught in Example III to persons afflicted with Alzheimer's Disease (and healthy patients), in cyclic treatment, stimulates the beneficial production of certain cytokines, particularly interferon gamma (IFN-γ) and tumor necrosis factor alpha (TNF-α), which patients with Alzheimer's Disease exhibit a diminished capacity for production of. IFN-γ is a potent immunomodulator that is critical for the development of the cytotoxic lymphocyte response (CTL). This immune response is considered to be very important in protecting humans and animals from variety of bacterial, viral and parasitic infections. The fact that TNF-α is also induced by Colostrinin is important because TNF-α is a major activator of macrophages, among other immune cells, which are important in host defense against infections. Also it is important to mention that the induction of these two cytokines was correlated with the increase in the proliferation of peripheral blood lymphocytes.

Example IX (page 19, line 40 to page 21, line 4) shows that administration of Colostrinin in tablet form as taught in Example III, in addition to inducing the beneficial production of cytokines in human patients afflicted with Alzheimer's Disease, also produces an improvement of contact and an uplift in mood in such patients. The phrase

"improvement of contact" means that the general awareness of the human patient and the human patient's response to external stimuli was increased. This may be objectively manifested as an improvement in participation of the human patient in daily activities by active, and not dormant, behavior. An "uplift in mood" means that improvements are observed in the human patient's general level of happiness and contentment.

The specification also discloses that instead of Colostrinin, a variety of disorders, especially Alzheimer's Disease, can be treated through the administration of an isolated nonapeptide ("NP") obtained from Colostrinin or by means of chemical synthesis that has the following composition and amino acid sequence: Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro (page 10, lines 5-15). Examples II and X show the isolation of NP and the use of NP in the treatment of Alzheimer's Disease, respectively. Administration of NP to patients afflicted with the early stages of Alzheimer's Disease induced a state of hyporeactivity or tolerance, which resulted in an improvement of contact and an uplift of mood in such patients (page 21, lines 7-22).

In view of the foregoing, applicants respectfully submit that the specification is fully enabling for claims of the scope presently presented for consideration. The specification clearly describes what Colostrinin is, how and where it can be obtained, how much should be administered to a human patient as a dietary supplement or to treat dementia and/or Alzheimer's Disease, in what forms the Colostrinin can be administered, a preferred regimen by which it can be administered, and the likely results to be derived from its administration. Applicants respectfully submit that one of ordinary

skill in the art could easily practice the invention as claimed based upon the teachings and disclosures set forth in the present specification. Reconsideration of the rejection of claims 15, 16, 24, 26-32 and 35 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claim Rejections - 35 U.S.C. §102

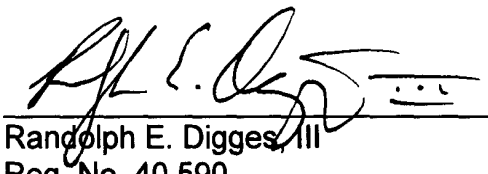
In the Office action of February 7, 2003 (Paper No. 26), claims 15, 16, 24, 26-32, 35, 40, 41, and 54 were rejected under 35 U.S.C. §102(a) as being anticipated by Inglot (Archivum Immunologiae et Therapiae Experimentalis, 1996, Vol. 44, pp. 215-224). However, in the Office action of February 28, 2003 (Paper No. 27), the rejection of such claims was withdrawn in view of a Declaration previously submitted by the applicant showing that the Inglot reference was actually published on October 8, 1996 after the October 3, 1996 priority date of the present application.

Conclusion

In view of the foregoing, applicants respectfully submit that claims 15, 16, 24, 26-32, 35, 40, 41, 54 and 58-68 are presently in condition for allowance, and a timely Notice to that effect is earnestly solicited.

Respectfully submitted,

RANKIN, HILL, PORTER & CLARK, L.L.P.



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A1(21) 322445 (22) 97 10 06 6(51) A61K 33/14 A61K 9/107

(31) 96 9612196 (32) 96 10 07 (33) FR

(71) LA ROCHE POSAY LABORATOIRE PHARMACEUTIQUE, La Roche Posay, FR

(72) Burnier Veronique

(54) **Emulsja woda w oleju o wysokiej zawrtości elektrolitu**

(57) Wynalazek ujawnia stabilną emulsję typu woda w oleju o wysokiej zawartości elektrolitu, zawierającą jako jeden ze składników co najmniej 2% wag. co najmniej jednej rozpuszczalnej w wodzie soli metalu, która jest zwłaszcza użyteczna do sterowania miejscowego, w szczególności w dermo-kosmetyce w celu traktowania podrażnionej i/lub wrażliwej skóry.

(22 zastrzeżenia)

A1(21) 323748 (22) 96 05 31 6(51) A61K 35/74

(31) 95 459058 (32) 95 06 02 (33) US

(86) 96 05 31 PCT/US96/08260

(87) 96 12 05 WO96/38159 PCT Gazette nr 53/96

(71) LAFOR LABORATORIES LIMITED, Newport Beach, US

(72) Ford Larry C.

(54) **Mikrokapsułkowane pałeczki mlekowe do stosowania w medycynie**

(57) Mikrokapsułkowane pałeczki mlekowe, będące składnikiem kompozycji farmaceutycznej, doustnie podaje się ssakom, w tym ludziom w celu leczenia lub zapobiegania wywołanym podawaniem antybiotyków lub innym przewlekłym lub ostrym biegunkom. Mikrokapsułkowane pałeczki mlekowe miejscowo podaje się na skórę w celu leczenia lub zapobiegania nawracającym zakażeniom skóry i poddaje się dopochwowo w celu leczenia lub zapobiegania drożdżowym zakażeniom pochwy.

(31 zastrzeżeń)

A1(21) 323735 (22) 96 05 24 6(51) A61K 38/00

(31) 95 468947 (32) 95 06 06 (33) US

(86) 96 05 24 PCT/US96/07756

(87) 96 12 12 WO96/39160 PCT Gazette nr 54/96

(71) BIOMEASURE INCORPORATED, Milford, US

(72) Shalaby Shalaby W., US; Jackson Steven A., US; Ignatious Francis, IN; Moreau Jacques-Pierre, US

(54) **Jonowe cząsteczkowe koniugaty N-acylowanych pochodnych poli(2-amino-2-dezoksy-D-glukozy) i polipeptydów**

(57) Ujawniono m.in. kopolimer obejmujący N-acylowaną pochodną poli(2-amino-2-dezoksy-D-glukozy) i kompozycję zawierającą wymieniony kopolimer i polipeptyd, obejmujący przynajmniej jedną skuteczną jonogeniczną aminę, przy czym przynajmniej 50% wag. wymienionego polipeptydu obecnego w wymienionej kompozycji jest jonowo związane z wymienionym polimerem.

(20 zastrzeżeń)

A1(21) 323595 (22) 96 05 20 6(51) A61K 38/15

(31) 95 19520275 (32) 95 06 02 (33) DE

(86) 96 05 20 PCT/EP96/02170

(87) 96 12 05 WO96/38165 PCT Gazette nr 53/96

(71) BAYER AKTIENGESELLSCHAFT, Leverkusen, DE

(72) Mencke Norbert, Harder Achim, Jeschke Peter, Helpap Barbara

(54) **Środki endopasożytobójcze**

(57) Wynalazek dotyczy mieszanin zawierających przynajmniej jedną awermektynę, 22,23-dihydroawermektynę B_1 (iwermektynę) albo milbemycynę z klasy makrocyklicznych laktonów w zestawieniu z cyklicznymi depsipeptydami, ewentualnie w obecności prazikwantelu lub epsiprantelu, do podwyższania działania endopasożytobójczego w środkach endopasożytobójczych.

(1 zastrzeżenie)

A1(21) 316416 (22) 96 10 03 6(51) A61K 38/17

(71) Polska Akademia Nauk Instytut Immunologii i Terapii Doświadczalnej imienia Ludwika Hirszfelda, Wrocław

(72) Janusz Maria, Dubowska-Inglot Anna, Lisowski Józef

(54) **Środek farmaceutyczny o działaniu immuno i psychotropowym, postać terapeutyczna środka farmaceutycznego o działaniu immuno i psychotropowym oraz sposób leczenia chorób o podłożu immunologicznym i psychicznym**

(57) Środek farmaceutyczny stanowi polipeptyd "PRP" dalej nazwany Colostrinin o ciężarze cząsteczkowym 18000, zawierający dużo reszt proliny (22%) i niepolarnych aminokwasów, bez reszt cukrowych i jest otrzymywany z siary dużych zwierząt hodowlanych, zwłaszcza owiec lub nonapeptyd, oznaczony jako "NP", o składzie i sekwencji aminokwasów: Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro i jest otrzymywany z polipeptydu Colostrinin poprzez trawienie chymotrypsyną lub na drodze syntezy chemicznej. Postać terapeutyczna w formie inlekcji i do wchłaniania przez ślinę oraz z przewodu pokarmowego w formie tabletki, lingwetki, żeli adhezyjnych oraz plastrów adhezyjnych zawiera na jednostkę dozowniczą 25 - 1000 µg wymienionych wyżej polipeptydu Colostrinin lub nonapeptydu "NP". Sposób leczenia polega na podawaniu w okresie 2 - 4 tygodni 1 - 2 jednostek terapeutycznych dziennie, z przerwą 2 - 4 tygodni i co najmniej jednym powtórzeniem cyklu.

(5 zastrzeżeń)

A1(21) 323736 (22) 96 06 03 6(51) A61K 38/18

(31) 95 478502 (32) 95 06 07 (33) US

(86) 96 06 03 PCT/US96/08474

(87) 96 12 19 WO96/40073 PCT Gazette nr 55/96

(71) ALKERMES CONTROLLED THERAPEUTICS, INC., Cambridge, US

(72) Zale Stephen E., Burke Paul A., Bernstein Howard, Brickner Avram

(54) **Kompozycja podtrzymująca uwalnianie nieagregowanej erytropojetyny**

(57) Kompozycja podtrzymująca uwalnianie nieagregowanej erytropojetyny (EPO) obejmuje a) polimerową matrycę z biokompatybilnego polimeru i b) cząstki aktywnej biologicznie, stabilizowanej przeciwko agregacji EPO, przy czym wymienione cząstki zawieszone są w biokompatybilnym polimerze. Spo-

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(57) Abstract

The use of Colostrinin as a medicament, particularly in the treatment of chronic disorders of the central nervous system and the immune system.

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U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (If applicable)
PCT/GB97/02721	10/03/97	

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☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

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Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
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Inventor's Signature	[signature]					Date	6.23.99
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